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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,178	07/08/2003	Dennis M. Brown	A-71462/RFT/THR (468899-3)	1122
7590	10/05/2004		EXAMINER TRINH, BA K	
Traci H. Ropp for Richard F. Trecartin Dorsey & Whitney LLP Intellectual Property Department Four Embarcadero Center, Suite 3400 San Francisco, CA 94111-4187			ART UNIT 1625	PAPER NUMBER

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/616,178

Applicant(s)

BROWN, DENNIS M.

Examiner

Ba K. Trinh

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12/10/2003.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☒ Claim(s) 3-4,22 is/are allowed.  
6) ☒ Claim(s) 1-2,5-21 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 08 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

Claims 1-22 are pending.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by the reaction in Scheme 1 page 207 of Brana et al( Eur. J. Med. Chem. ).

Claims 5-11,14-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Compound (I) in the Abstract and lines 21-62 column 6 of Ajami et al.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brana et al and Brana et al I ( US 5,420,137) in view of Brana et al II ( US 5,552,544).

Brana et al teaches an acetyl ammonium salt of naphthalimide; note compounds 43,44,54,59 and 60 in Table I page 208 of the reference. The compounds can be made by the acetylation method as disclosed in the second paragraph column 1 page 211 of the same. Brana et al I teaches monohydrochloride and monomethanesulfonate of amonafide; note the Abstract. The prior art do not specifically teach the current diammonium salt of the naphthalimide which has two counter ions attached to the two Nitrogen atoms. Brana et al teaches an analogous naphthalimide( or amonafide) and its salts with both organic and inorganic acids; note lines 15-48 column 1 of the patent. The salts can be made by reacting the naphthalimide with an acid; note lines 27-30 column 2 of the same. This teachings imply that the acid reacts with the amino group to form the ammonium salt. Thus, it would be prima facie obvious to modify the teachings of Brana et al and Brana et al I by reacting the naphthalimide with an acid to make the monoammonium salt first, and then with the excess acid to make a diammonium salt from the monoammonium salt using the teachings of Brana et al II.. It is also obvious that acid is reactive to amino group, thus, the acid would react with all the amino group(s) available of the naphthalimide; i.e., monoammonium salt and diammonium salt will be formed in the reaction medium at a different ratio. Thus, the claimed invention would be deemed obvious over the prior art teachings in the absence of unexpected and/or unobvious results.

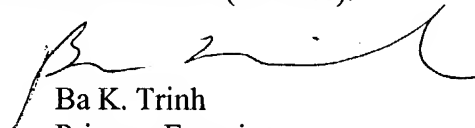
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Claims 3-4 and 22 are allowable since the prior art fail to teach and/or fairly suggest the claimed processes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ba K. Trinh whose telephone number is (571) 272-0695. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ba K. Trinh  
Primary Examiner  
Art Unit 1625

TRINH/BKT  
30 September 2004